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OM—09—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm (Second Semester) EXAMINATION

July, 2026

HAZARDS AND SAFETY MANAGEMENT

(MQA-201-T)

(Thursday, 2-7-2026)

Time : 2.00 p.m. to 5.00 p.m.

Time—3 Hours

Maximum Marks—75

N.B. :— (i) All questions are compulsory.

(ii) Figures to the right indicate full marks.

(iii) Answer to the point only.

1. Answer the following questions :

10×2=20

- (a) Give the significance of self-protective measures against workplace hazards.**
- (b) Give the objectives of Factories Acts 1948 and Bihar Factories Rules 1950.**
- (c) What is the importance of passivation ?**

P.T.O.



- (d) Write pictogram used in biohazards and irritant chemicals.
- (e) Enlist hazards based on radioisotopes.
- (f) Mention any *four* safety guidelines according to ICH.
- (g) Write the important components of an ecosystem.
- (h) Write the significance of food chains and food webs.
- (i) Write sources of air pollutions.
- (j) What is the benefits of oxygen displacing gases management ?

2. Answer any *two* of the following :

2×10=20

- (a) What are BOD and COD ? Discuss effluent treatment procedures and determination of contaminations.
- (b) Write the types of fire extinguishers and explain critical hazard management system.
- (c) Discuss mechanism and various management strategies and approaches to solve problems associated water and mineral resources.

3. Answer any *seven* of the following :

7×5=35

- (a) Explain air circulation maintenance system in industry for sterile area.
- (b) Discuss causes, effects and solutions to environmental degradations.



- (c) Explain in brief multiphase reaction, transport effect and global rates under fire and explosion.
- (d) Describe various hazards created during organic synthesis.
- (e) Discuss various prevention and protection management systems to avoid hazard in industry.
- (f) Explain relief system-relief valves and scrubbers used to protect from hazards.
- (g) Describe critical training system for risk management.
- (h) Explain various strategies and tools used to ensure safety standards in pharmaceuticals to avoid chemical hazards.
- (i) Write various problems arises in connection with land resources and energy resources in current era.

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OM—37—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (Second Semester) EXAMINATION

July 2026

AUDIT AND REGULATORY COMPLIANCE

(MQA-203T)

(Tuesday, 7-7-2026)

Time : 2.00 p.m. to 5.00 p.m.

Time—3 Hours

Maximum Marks—75

N.B. :— (i) All questions are compulsory.

(ii) Answer to the point only.

(iii) Figures to the right indicates full marks.

1. Answer the following questions :

10×2=20

(a) What is bulk drug ?

(b) What is critical system ?

(c) What is microbial specification of purified water and water for injection ?

(d) Define grade A, B, C and D as per the recommended limits for microbial contamination.

P.T.O.



- (e) What are the types of audit ?
- (f) Define quality audit.
- (g) Write down in brief classification of audit deficiencies.
- (h) What is ETP ?
- (i) What is HVAC ?
- (j) What is dispensing ?

2. Solve *two* out of three :

2×10=20

- (a) Write in detail about WHO–CGMP regulations.
- (b) Write in detail about transitioning of quality system approach and discuss about audit checklist for drug industries.
- (c) Discuss in detail auditing of microbiology laboratory.

3. Solve *seven* out of nine :

7×5=35

- (a) Discuss the functions of quality assurance.
- (b) Discuss about the management responsibilities in developing the quality system.
- (c) Discuss about the vendor qualification activities for active pharmaceutical ingredient.



- (d) Discuss in detail about the auditing of production department.
- (e) Explain the validation of HVAC system.
- (f) Discuss in detail about the effluent treatment plant.
- (g) Discuss the audit of warehouse, weighing and granulation.
- (h) Discuss in detail about sterile production and packaging.
- (i) Discuss auditing in engineering department.